AF JW

TRANSMITTAL LETTER (General - Patent Pending)	Docket No. 05090001BA

In Re Application Of: **Okada et al.**

Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
10/035,156	01/04/2002	B. Nguyen	30743	1641	2583

Title: **IMMUNOASSAY METHOD AND IMMUNOASSAY KIT**

COMMISSIONER FOR PATENTS:

Transmitted herewith is:

Response to Notice of Non-Compliant Appeal Brief w/ copy of Notice, copy originally filed appeal brief and date-stamped receipt
Postcard

in the above identified application.

- ☒ No additional fee is required.
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Signature

Dated: **August 18, 2005**

Michael E. Whitham
Reg. No. 32,635

Whitham, Curtis & Christofferson, P.C.
11491 Sunset Hills Road, Suite 340
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I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to the "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on

_____.
(Date)

Signature of Person Mailing Correspondence

Typed or Printed Name of Person Mailing Correspondence

cc:

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of

K. Okada et al. Confirmation No.2583

Serial No. 10/035,156 Group Art Unit 1641

Filed January 4, 2002 Examiner: B. T. L. Nguyen

For IMMUNOASSAY METHOD AND IMMUNOASSAY KIT

Commissioner for Patents
PO Box 1450
Alexandria, Virginia 22313-1450

RESPONSE TO NOTICE OF NON-COMPLIANT APPEAL BRIEF

Sir:

Attached is a copy of a notice of non-compliant appeal brief mailed August 8, 2005.

Also attached is a copy of the appeal brief as filed May 21, 2005 together with a date stamped receipt.

As was discussed with Examiner Nguyen by telephone call on August 17, 2005, the Appeal Brief, as filed on May 31, 2005, includes

a) All of the items required under 37 CFR 41.27(c) under the proper headings and in the proper order (as was acknowledged by the Examiner during the telephone call, reference to 37 CFR 1.192 is now no longer proper-for the Examiner's convenience a copy of new part 41 of the Patent Rules is enclosed);

b) A concise explanation of the subject matter defined in each of the independent claims involved in the appeal with reference to the specification by page and line number (pages 7-11 of the brief specifically identify independent claims 1, 6 and 7 (full text of the claims in the claims section of pages 25-27), and makes numerous references to page and line numbers in the specification (see, for example, first paragraph on page 7, first paragraph on page 8, second paragraph on page 9; fifth paragraph on page 10; first paragraph on page 11)

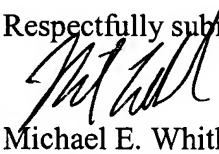
In view of this, and based on the telephonic discussions with Examiner Nguyen, it appears that the Notice of Non-Compliant Appeal Brief was rendered

in error and should now be withdrawn.

If any further outstanding matters need to be addressed, please contact the undersigned at the telephone number below.

A provisional petition is hereby made for any extension of time necessary for the continued pendency during the life of this application. Please charge any fees for such provisional petition and any deficiencies in fees and credit any overpayment of fees to Attorney's Deposit Account No. 50-2041.

Respectfully submitted,



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,156	01/04/2002	Keisaku Okada	05090001BA	2583

30743 7590 08/08/2005

EXAMINER	

WHITHAM, CURTIS & CHRISTOFFERSON, P.C.
11491 SUNSET HILLS ROAD
SUITE 340
RESTON, VA 20190

ART UNIT	PAPER NUMBER

DATE MAILED: 08/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Notification of Non-Compliant Appeal Brief (37 CFR 41.37)	Application No. 10/035,156	Applicant(s) OKADA ET AL.	
	Examiner Bao-Thuy L. Nguyen	Art Unit 1641	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

The Appeal Brief filed on *31 May 2005* is defective for failure to comply with one or more provisions of 37 CFR 41.37.

To avoid dismissal of the appeal, applicant must file a complete new brief in compliance with 37 CFR 41.37 within **ONE MONTH or THIRTY DAYS** from the mailing date of this Notification, whichever is longer. **EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136.**

1. ☒ The brief does not contain the items required under 37 CFR 41.37(c), or the items are not under the proper heading or in the proper order.

2. ☐ The brief does not contain a statement of the status of all claims, (e.g., rejected, allowed or confirmed, withdrawn, objected to, canceled), or does not identify the appealed claims (37 CFR 41.37(c)(1)(iii)).

3. ☐ At least one amendment has been filed subsequent to the final rejection, and the brief does not contain a statement of the status of each such amendment (37 CFR 41.37(c)(1)(iv)).

4. ☒ (a) The brief does not contain a concise explanation of the subject matter defined in each of the independent claims involved in the appeal, referring to the specification by page and line number and to the drawings, if any, by reference characters; and/or (b) the brief fails to: (1) identify, for each independent claim involved in the appeal and for each dependent claim argued separately, every means plus function and step plus function under 35 U.S.C. 112, sixth paragraph, and/or (2) set forth the structure, material, or acts described in the specification as corresponding to each claimed function with reference to the specification by page and line number, and to the drawings, if any, by reference characters (37 CFR 41.37(c)(1)(v)).

5. ☐ The brief does not contain a concise statement of each ground of rejection presented for review (37 CFR 41.37(c)(1)(vi))

6. ☐ The brief does not present an argument under a separate heading for each ground of rejection on appeal (37 CFR 41.37(c)(1)(vii)).

7. ☐ The brief does not contain a correct copy of the appealed claims as an appendix thereto (37 CFR 41.37(c)(1)(viii)).

8. ☐ The brief does not contain copies of the evidence submitted under 37 CFR 1.130, 1.131, or 1.132 or of any other evidence entered by the examiner and relied upon by appellant in the appeal, along with a statement setting forth where in the record that evidence was entered by the examiner, as an appendix thereto (37 CFR 41.37(c)(1)(ix)).

9. ☐ The brief does not contain copies of the decisions rendered by a court or the Board in the proceeding identified in the Related Appeals and Interferences section of the brief as an appendix thereto (37 CFR 41.37(c)(1)(x)).

10. ☒ Other (including any explanation in support of the above items):

See attached.

Bao-Thuy L. Nguyen
Primary Examiner
Art Unit: 1641

Defective Appeal Brief

1. The brief does not contain the items of the brief required by 37 CFR 1.192 (c) under the appropriate heading and/or in the order indicated. See also MPEP §1206.

- Item VI should be listed as Issues instead of Grounds of rejection to be reviewed on appeal.
- The brief lacks a grouping of the claims in items VII, i.e. whether the claims stand or fall together.

The appropriate headings are as follow:

I. REAL PARTY IN INTEREST

II. RELATED APPEALS AND INTERFERENCES

III. STATUS OF CLAIMS

IV. STATUS OF AMENDMENTS

V. SUMMARY OF THE INVENTION

VI. ISSUES

VII. GROUPING OF CLAIMS

VIII. ARGUMENTS

2. The brief does not contain a *concise explanation* of the invention defined in the claims involved in the appeal, which refers to the specification by page and line number, and to the drawing, if any, by reference characters as required by 37 CFR 1.192(c)(5).

3. Appellant is required to comply with provisions of 37 CFR 1.192(c).

To avoid dismissal of the appeal, Appellant must comply with the provisions of 37 CFR 1.192(c) within the longest of any of the following TIME PERIODS: (1) ONE MONTH or THIRTY DAYS, whichever is longer, from the mailing of this communication; (2) within the time period for reply to the action from which appeal has been taken; or (3) within two months from the date of the notice of appeal under 37 CFR 1.191. Extensions of these time periods may be granted under 37 CFR 1.136.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Thursday from 8:00 a.m. -3:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BAO-THUY L. NGUYEN
PRIMARY EXAMINER
8/4/05

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

Docket Number (Optional)	Application Number
05090001BA	10/035,156
Applicant(s) K. Okada	
Filing Date 1/4/02	**Group Art Unit** 1641

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	REF	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
BTN	AA	5,141,850	8/25/92	Cole et al.			
	AB	5,242,804	9/7/93	Bahar et al.			
		5,965,458	10/12/99	Kouvonen et al.			
	AD	5,512,282	4/30/96	Krivan et al.			
BTN	AE	6,080,400	6/27/00	Williams et al.			

FOREIGN PATENT DOCUMENTS

	REF	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	Translation YES	Translation NO

OTHER DOCUMENTS *(Including Author, Title, Date, Pertinent Pages, Etc.)*

EXAMINER	DATE CONSIDERED
	9/2004

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

-FORM PTO-1449 (Modified)

LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

ATTY. DOCKET NO.	SERIAL NO.
20619DIV	Unassigned
APPLICANT: K. Okada et al.	
FILING DATE: Concurrently	GROUP: Unassigned

J1046 U.S. PTO 10/035156 01/04/02

REFERENCE DESIGNATION

U.S. PATENT DOCUMENTS

EXAMINER INITIALS		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE (IF APPRO.)
BTN		4,647,654	03-03-87	Knowles, et al.			

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO
BTN		WO 92/02820	02-20-92	PCT			X	
		DE 196 16 321 A1	10-30-97	Germany				X
BTN		0 315 866 A1	05-17-89	Europe			X	

OTHER ART (Including Author, Title, Date, Pertinent Pages, etc.)

EXAMINER M Nguyen

DATE CONSIDERED 9/2004

Docket No. D509000/BA In re: ✓ patent/___ trademark application of Hand Delivered

Applicant(s) K. Okada, et al

Serial No. 10/035,156 Date Filed 1-4-02

Papers filed herewith on 5-31-05

✓ Fees $ ___ Deposit Account No. (if applicable) CAF # 8027

(___ filing fee; ___ Assignment charge; ___ Extension of Time;

___ issue fee/advance copies; 500 other Appeal Brief fee)

___ Amendment ___ Notice of Appeal ✓ X3 Appeal Brief

___ Sheets of ___ Drawings ___ Proposed Drawing Corrections (w/___ drawings)

___ Change of Address ___ Request for Extension of Time

___ Assignment ___ Recordation Form Cover Sheet

___ Information Disclosure Statement ___ PTO-1449 and associated art (___ docs.)

___ Priority Document(s) ___ Other Rtc/plea

TRANSMITTAL OF APPEAL BRIEF (Large Entity)	Docket No. 05090001BA

In Re Application Of: **K. Okada, et al.**

Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
10/035,156	January 4, 2002	B. T. L. Nguyen	30743	1641	2583

Invention: **IMMUNOASSAY METHOD AND IMMUNOASSAY KIT**

COMMISSIONER FOR PATENTS:

Transmitted herewith in triplicate is the Appeal Brief in this application, with respect to the Notice of Appeal filed on **April 18, 2005**

The fee for filing this Appeal Brief is: **$500.00**

☒ A check in the amount of the fee is enclosed.

☐ The Director has already been authorized to charge fees in this application to a Deposit Account.

☒ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. **50-2041**

☐ Payment by credit card. Form PTO-2038 is attached.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

Signature

Dated: **May 31, 2005**

Ruth Tyler-Cross
Reg no. 45,922
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703-787-9400

cc:

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on

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(Date)

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re patent application of Okada et al.
Serial No. 10/035,156
Filed January 4, 2002
For: ***IMMUNOASSAY METHOD AND IMMUNOASSAY KIT***

Group Art Unit 1641
Examiner Nguyen
Confirmation No. 2583

MAIL STOP APPEAL BRIEF
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

APPELLANTS' BRIEF UNDER 37 C.F.R. § 41.37

In response to the action of the Primary Examiner in finally rejecting claims 1-7 of this application, a Notice of Appeal was timely filed April18, 2005. This brief, which is filed herewith in triplicate, is in furtherance of the Notice of Appeal.

This brief contains these items under the following headings and in the order set forth below, as required under 37 C.F.R. § 41.37:

I. REAL PARTY IN INTEREST
II. RELATED APPEALS AND INTERFERENCES
III. STATUS OF CLAIMS
IV. STATUS OF AMENDMENTS
V. SUMMARY OF CLAIMED SUBJECT MATTER
VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL
VII. ARGUMENTS
☐ ARGUMENT VIIA. REJECTIONS UNDER 35 U.S.C. §112, FIRST PARAGRAPH

☐ ARGUMENT VIIB. REJECTIONS UNDER 35 U.S.C. §112, SECOND PARAGRAPH

☐ ARGUMENT VIIC. REJECTIONS UNDER 35 U.S.C. §102

☑ ARGUMENT VIID. REJECTIONS UNDER 35 U.S.C. §103

☐ ARGUMENT VIIE. REJECTION OTHER THAN 35 U.S.C. §§102, 103 AND 112

VIII. CLAIMS APPENDIX

IX. EVIDENCE APPENDIX

X. RELATED PROCEEDINGS APPENDIX

I. REAL PARTY IN INTEREST

The real party in interest in the appeal is:

☐ the party named in the caption of this brief.

☑ the following party:

Netto Denko Corporation of Osaka, Japan.

II. RELATED APPEALS AND INTERFERENCES

With respect to other appeals or interferences that will directly affect, or be directly affected by, or have a bearing on the Board's decision in this appeal:

☑ there are no such appeals or interferences.

☐ these are as follows:

III. STATUS OF CLAIMS

The status of the claims in this application is as follows:

A. Total number of claims in Application

The claims in the application are: Claims 1-7, totaling 7 claims

B. Status of all the claims:

1. Claims cancelled: None
2. Claims withdrawn from consideration but not cancelled: None
3. Claims pending: Claims 1-7
4. Claims allowed: None
5. Claims rejected: Claims 1-7
6. Claims objected to: None

C. Claims on Appeal.

The claims on appeal are: Claims 1-7

IV. STATUS OF AMENDMENTS

The status of amendments filed subsequent to the final rejection is as follows: There are no after-final amendments.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER

The claimed invention, defined in independent claims 1, 6 and 7, and in dependent claims 2-5, is directed to the detection of at least two different test substances (e.g. verotoxin producing *Escherichia coli* and verotoxin; verotoxin and human hemoglobin; and verotoxin producing *Escherichia coli* and human hemoglobin) in a single test using the same base material, i.e. on a single test strip (see Technical Field of the Iinvention on page 1; first paragraph of the Summary of the Invention on page 3; and the last paragraph of page 21). The present invention thus allows the detection of diverse but related materials, detecting two of: the causative agent of a disease (*Escherichia coli* bacteria), the agent produced by the bacterium that is the immediate cause of disease (verotoxin); and the physiological effect that is produced (hemoglobin, e.g. in feces as a result of internal hemorrhage). This aspect of the invention is disclosed at least on page 2 of the application, where it is noted that the assay kit will detect "...verotoxin and human hemoglobin associated with internal hemorrhage...".

Prior to the claimed invention, separate tests for the detection of verotoxin and the bacteria that produce verotoxin (*Escherichia coli*) were employed. The tests were typically conducted in a time-consuming and labor intensive manner. For example, the bacteria were detected by culturing a test sample thought to harbor the bacteria, and then detecting bacterial antigens (e.g. O157) using an enzyme-linked immunosorbent assay (ELISA) method, or by latex agglutination. In order to detect the verotoxin that is produced by the bacterium, a different test was used, which also involved culture of a sample and detection of verotoxin 1 and/or verotoxin 2 by latex agglutination. These methods detected *E. coli* antigen and verotoxin in single, separate tests, and both required culturing of the sample prior to detection. The present invention provides a streamlined, efficient immunity chromatography method to permit rapid and highly accurate detection of the two target substances in a single test.

The method involves the simultaneous detection of at least two target assay substances. The target substances may be located in a liquid test sample, and detection of the target substances occurs during movement of the liquid test sample up a test strip

(immunity chromatography, see page 3, lines 3–4). Each target assay substance is detected by binding to two different immunity substances, e.g. antibodies, both of which are specific for the target substance (page 5, lines 25-26). One of the antibodies (the "first immunity substance") unlabeled and is immobilized on the test strip; the other (the "second immunity substance") is labeled and is not immobilized, but is present either 1) in a liquid (see page 9, lines 16-17), or 2) temporarily dried onto the test strip (see page 10, lines 2-5).

If in a liquid, the second immunity substance may be in the liquid test sample, where it binds to the target substance to form a complex. The complex then migrates up the test strip, encounters the immobilized first immunity substance, and is sequestered there. Alternatively, the second immunity substance may be in a liquid separate form the test sample. In this case, the test sample liquid containing the target substance first moves up the strip, where the target substance binds to and is sequestered by the first immunity substance. Then, a liquid containing the labeled second immunity substance moves up the strip, allowing the second immunity substance to bind to the sequestered target substance. A third variation is that the test sample itself may be dried onto the test strip (below the immobilized first immunity substance). The liquid containing the second immunity substance is allowed to move up the strip, the target substance is dissolved by the liquid and binds to the second immunity substance, and the complex continues to move up the strip to encounter the immobilized first immunity substance, where it is sequestered by specific binding between the target substance (in the complex) and the immobilized first immunity substance.

On the other hand, if the second immunity substance is dried onto the test strip, it is located at a position near the end that will be immersed in (or other wise receive) the test sample. In this case, the liquid containing the target substance migrates up the test strip, and the liquid dissolves the second immunity substance, which then binds to the target substance, forming a complex. The complex then migrates up the strip and encounters the immobilized first immunity substance, where it is sequestered by specific binding between the target substance (in the complex) and the immobilized first

immunity substance. According to the invention, two target substances in a single test sample may be detected in this manner on a single strip by using two different labeled second immunity substances, and by immobilizing two different first immunity substances at different positions on a single test strip.

Both of the two antibodies for a single target substance may be polyclonal antibodies, or one may be monoclonal and the other polyclonal, or both may be monoclonal, so long as both monoclonals recognize and bind to different epitopes of the target substance (page 6, lines 4-7).

Specifically, independent claim 1 is directed to an immunoassay method for detecting, in a single assay, two target substances selected from one of three possible combinations of two substances:

1) verotoxin producing *Escherichia coli* and verotoxin;

2) verotoxin and human hemoglobin; and

3) verotoxin producing *Escherichia coli* and human hemoglobin.

Independent claim 6 is directed to an immunoassay device for carrying out the method, and independent claim 7 is directed to an immunoassay kit for carrying out the method.

The method of claim 1 comprises two steps:

Step 1 involves: bringing an immobilized phase comprising (at different positions on a water-absorbable base material) at least two different first immunity substances that are specific for assay target substances in a test sample into contact with a test sample and a liquid containing second immunity substances. Each of the second immunity substances is labeled with colored latex particles, and is capable of binding specifically one of the target substances, thereby forming a labeled target substance-second immunity substance complex. The complexes also bind with respective first immunity substances at the immobilized phase, i.e. they are sequestered at the immobilized phase, by the specific binding between a first immunity substance and the target substance of the complex. The binding of a target substance to the first and second immunity substances may occur in any order, i.e. the target substance may first bind a labeled second immunity substance to form a complex, and the complex then binds to an immobilized first immunity substance

specific for the target substance. Alternatively, the target substance may first bind to the immobilized first immunity substance, and the labeled second immunity substance may then bind to the target substance that is bound (immobilized) with the first immunity substance.

The second step of the method involves: detecting the labeled immunity substance complex (the label being derived from the second immunity substance).

Thus, in all embodiments of the invention, target substances (if present) are located in the test sample, and will eventually be immobilized on the strip by first immobilized immunity substances that are specific for each of them. An immobilized target substance bound to the first immunity substance would not be readily detectable. Detection of the bound target substance is made possible by the binding of the labeled second immunity substance.

The dependent claims recite features of the invention with respect to the order in which the reactive substances make contact with one another, as follows:

Claim 2: Contact is made by flowing the test sample so that it is absorbed from one end of the water-absorbable base material, thereby to bind the complex with the first immunity substance; (i.e. the complex between the target substance and the second labeled immunity substance is made first, in the liquid test sample itself; then the liquid containing the complex flows up the strip to bind and be sequestered by the first immunity substance, which is immobilized on the strip; see also the fourth paragraph of page 11, and Figures 1 and 2);

Claim 3: Contact is made by flowing the test sample so that it is absorbed from one end of the water-absorbable base material, thereby to bind the assay target substance with the first immunity substance, and then flowing the liquid to allow absorption thereof by the base material, thereby to bind the second immunity substance with the assay target substance (i.e. two steps are carried out: first, the liquid sample containing the target substance flows up the strip and binds and is sequestered by the first immunity substance; second, a liquid with the labeled second immunity substance flows up the strip and binds to the test substance that is bound to the first immunity substance on the strip, thereby

labeling the test substance, see also last paragraph of page 11, which continues onto page 12, and Figures 1 and 2).

Claim 4: Contact is made by absorbing the test sample to the strip halfway up to the immobilized phase, and allowing the liquid containing the second immunity substance to be absorbed from one end of the water-soluble base material and flow up the strip, thus encountering the test substance and forming a complex between the test substance and the second immunity substance , followed by binding the complex with the first immunity substance at the immobilized phase (i.e. sample is absorbed onto the strip in the middle, a liquid containing the second immunity substance flows up the strip and the second immunity substance binds the test substance, forming a complex, then the complex continues to travel up the strip and binds the first immunity substance at the immobilized phase; see also the first complete paragraph of page 12).

Claim 5: wherein contact is made by positioning the second immunity substance half way up the strip and drying the strip; the test sample containing the test substance is then absorbed from one end of the strip forming a complex with the second immunity substance , followed by binding of the complex to the immobilized first immunity substance (i.e. second immunity substance, so that a mobile test substance -second immunity substance complex is formed. The complex continues to flow up the strip until it encounters the first immunity substance, whereupon the test substance is bound to and sequestered by the first immunity substance; see also paragraph number 6 on page 4 and Figures 3 and 4).

In summary, as recited in claims 1, 6, and 7, the present invention provides a method, device and kit (respectively) for detecting on a single test strip, two substances:

1) verotoxin producing *Escherichia coli* and verotoxin;

2) verotoxin and human hemoglobin; or

3) verotoxin producing *Escherichia coli* and human hemoglobin.

Prior to the present invention, no single test was available for the simultaneous detection of any two of these entities.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The sole issue presented in this Appeal is whether Claims 1-7 are obvious over a combination of U.S. Patent 5,965,458 to Kouvonen et al. ("Kouvonen") in view of U.S. patent 6,080,400 to Williams et al. ("Williams") and U.S. patent 5,512,282 to Krivan et al. ("Krivan").

ARGUMENT VIIA. REJECTIONS UNDER 35 U.S.C. §112, FIRST PARAGRAPH

There are no rejections under 35 U.S.C. §112, first paragraph.

ARGUMENT VIIB. REJECTIONS UNDER 35 U.S.C. §112, SECOND PARAGRAPH

There are no rejections under 35 U.S.C. §112, second paragraph.

ARGUMENT VIIC. REJECTIONS UNDER 35 U.S.C. §102

There are no rejections under 35 U.S.C. §102.

ARGUMENT VIID. REJECTIONS UNDER 35 U.S.C. §103

The Prior Art

Pursuant to an Office Action dated January 24, 2005, (the "Final Rejection"), claims 1-7 were erroneously rejected under 35 U.S.C. §103 as unpatentable over a combination of U.S. Patent 5,965,458 to Kouvonen et al. ("Kouvonen") in view of U.S. patent 6,080,400 to Williams et al. ("Williams") and U.S. patent 5,512,282 to Krivan et al. ("Krivan"). Applicants respectfully submit that claims 1-7 are not obvious over the combination put forth by the Examiner, since, among other considerations, none of the references shows or suggests an assay for simultaneously detecting two substances from the following group of three possible combinations of two substances: verotoxin producing *Escherichia coli* and verotoxin; verotoxin and human hemoglobin; or verotoxin producing *Escherichia coli* and human hemoglobin.

Kouvonen (U.S. patent 5,965,458)

The focus of Kouvonen is the development of an improved test strip for rapid immunoassays. Immunoassay strips with immobilized antibodies were well known prior to Kouvonen and many are described beginning in column 2 at line13 and ending column 3 at line 11. The rationale for developing yet another test strip is given in column 3 at lines 12-22, which describes the need for a test strip that is very simple, and that can be used almost anywhere (even without electricity or clean water) and even by untrained personnel. The test strip should be "rapid, sensitive and reliable" (column 3, lines 18-19), and construction of the strip should be simple enough to "allow manufacturing without complicated methods" (column 3, lines 19-21). Nevertheless, the product should be strong enough to "withstand environmental field conditions" (column 3, line 22).

The entire focus of Kouvonen is the design of a test strip that meets these criteria. The initial description of the innovative strip in the patent states that the structure is "simple and advantageous in view of manufacture"(column 3, lines 24-25 and 28-30). The use of the strip involves simply dipping the test strip into a sample and observing the results (column 3, lines 25-26), however the unique, distinguishing feature of the test strip is that "the essential reactions take place at a protected chamber-like gap" (column 3,

lines 27-28). This feature is spelled out in great detail in the specification, and is clearly illustrated in Figures 1-3. For example, in column 3 at lines 44-48, the following description is given: "Said test strip is characterized in that said backing and said membrane limit between themselves an *air gap which it open at its edges*. Said chamber will function as a *sheltered reaction chamber* for the immunological reaction taking place in said membrane." (Emphasis added.)

A more detailed description of the strip, and particularly of the air gap/sheltered reaction chamber is given in conjunction with the description of the figures, a copy of which is presented in Evidence Appendix IX. Indeed the design is relatively simple, involving, with reference to exploded Figure 1B, backing sheet 1 and cover 6, which enclose absorbing pads 3 and 5, with test membrane 2 between and immediately adjacent to cover 6 (in Figure 1B) or to backing sheet 1 (Figure 3). In either case, absorbing pads 3 and 5 are "separated by gap 4 which is long enough to extend over the reaction areas in test membrane 2" (column 4, lines 61-62). Gap 4 is clearly depicted in Figures 1A, 1B and 3, and is the distinctive air gap/sheltered reaction chamber of the test strip of the invention. The reactive species of the test strip include zone 7 on pad 3, which contains a dried labeled reagent, and at least one antibody line 8 (and possibly control line(s) 9) on membrane 2. During use of the strip, a test sample moves by lateral flow (column 5, line 37) up the strip and any analytes in the sample encounter the dried labeled reagent of zone 7 and the antibody of line 8. A key feature of the invention is that, during the flow of the sample, the gap 4 between test membrane 2 and backing 1 provides a small chamber, open on both sides, where the liquid flow on membrane 2 is undisturbed, i.e. the air gap/sheltered reaction chamber. Further, since gap 4 is narrow, the atmosphere in the gap retains its humidity and any drying caused by air will not disturb the flow of liquid (column 5, lines 6-13).

These features of the invention are reflected in the claims of Kouvonen. Claim 1 recites that the cover of the test strip is positioned over the supporting pads in a spaced apart relationship to define "top and bottom boundaries of an air gap" which is "open at its edges".

Applicant notes that the problem solved by the invention of Kouvonen is the previous lack of simple, reliable test strips that are easy to manufacture. The solution to the problem, according to Kouvonen, is the test strip with an air gap/sheltered reaction chamber. The discussion of what or how many substances could be detected with the strip is confined to general "laundry lists" of potential substances of interest, for example in columns 8 and 9, where many substances are listed. Applicant submits that in these lists, there is no suggestion of particular substances that are well suited for detection by the strip, and absolutely no suggestion or discussion of the benefits of pairing the detection of any two particular substances. The detection of hemoglobin is mentioned (column 8, line 30); the detection of microorganisms is mentioned (column 9, line 25). However, there is neither a showing or suggestion of the detection on a single strip, or advantages thereof, of the combinations of substances recited in the claims of the present invention (verotoxin producing *Escherichia coli* and verotoxin; verotoxin and human hemoglobin; and verotoxin producing *Escherichia coli* and human hemoglobin). Rather, the invention of Kouvonen involves the design of the test strip itself.

Applicant further notes that the design requirements of the strip of Kouvonen differ from those of the present invention. In all embodiments of the strip of Kouvonen, zone 7 in absorbing pad 3 contains a dried labeled reagent, e.g. latex, metal colloid or other particles as well as soluble molecules (column 4, lines 56-57; column 5, lines 43-44), and antibodies are immobilized at antibody lines 8 (column 4, lines 64-65). Further, claim 1 of Kouvonen recites "at least one label zone downstream of said sample absorbing end, and at least one immunochemical reagent zone located downstream of said label zone". This is in contrast to the present invention in which the label is attached to the second immunity substance, which may be either in a mobile liquid phase (claims 2-4) or dried onto the strip (claim 5).

Further, the method of the present invention need not be carried out on a strip per se, but may be carried out using a water-absorbable base material of any shape, so long as the assay target substance can be developed thereon (page 7, third full paragraph). For example, the method could utilize a rod shaped base material. In contrast, claim 1 of

Kouvenon recites a "test strip".

While Kouvenon broadly recites that different analytes may be detected on the test strip disclosed therein, there is absolutely no disclosure or suggestion therein of detecting two different kinds of assay target substances as is done in the method of the present invention. At most, Kouvenon teaches detecting two types of similar analytes. For example, Example 3 of Kouvenon describes a test strip designed to determine the presence of human blood by detecting human hemoglobin and human albumin, both of which are proteins found in the blood. In contrast, the present invention allows the detection of diverse materials such as verotoxin and the bacteria that produce it, allowing the detection of two of: the causative agent of a disease (the bacteria), the agent it produces to cause disease symptoms (verotoxin), and the physiological effect that is produced (hemoglobin). No such detection system is shown or suggested by Kouvenon.

Williams (U.S. patent 6,080,400)

The primary focus of Williams is the provision of antitoxin therapy to neutralize the pathological effects of verotoxins produced by *Escherichia coli*. The background section of the application describes in detail the untoward effects of verotoxins (see section C, beginning in column 4 at line 13), and also describes the lack of available treatments (see section E, beginning in column 9 at line 34). The last sentence of section E (column 10, lines 13-15) states that "What is needed is a means to block the progression of disease, without the complications associated with antimicrobial treatment." The invention supplies such a means, as stated in column 16 at lines 62-63: "The present invention relates to antitoxin therapy for humans and other animals." In addition, the use of antitoxin for diagnostic purposes, e.g. to detect the presence of toxins in samples, is also disclosed (column 18, lines 12-13; column 21, lines 8-10).

Antibodies to *E. coli* verotoxins were known prior to the invention of Williams. Some examples are described in section A (column 24 beginning at line 42). Thus, the ability of make antibodies to verotoxin is not the point of the Williams invention. Rather, a key feature is the *method* of producing the antibodies. Problems with prior art approaches include suboptimal recovery of the protein to be used to elicit antibody

production (column 22, lines 1-8 and 15-25), as well as problems with production of neutralizing antibodies, for which "success has not been consistently achieved" (column 24, lines 49-50).

The Williams invention addresses these problems by providing methods of recovering relatively high levels of protein in which the conformation of the protein is correct, i.e. the protein is in its *native conformation* (see column 22, lines26-43), and to produce superior, improved antitoxin to the native form of the protein *in avian species* (see column 26, lines 4-6 and 14-15).

Williams states that antitoxin produced in this manner can be used therapeutically or for diagnostic purposes. Williams discussion of the diagnostic use of the antibodies is given briefly in column 18, at lines 12-36, and in detail in column 30 in section VII, which begins at line 21. The statement is made at column 30, lines 22-23 that "The invention contemplates detecting bacterial toxin in a sample." Section VII goes on to describe the types of samples that can be analyzed (column 30, lines 28-49); the steps of carrying out a competitive immunoassay (column 30, lines 50-67 and column 31, lines 1-3); the steps of carrying out a "sandwich" assay (column 31, lines 4-20); and other various embodiments (e.g. pouring sample liquids over antibody immobilized on a support). Applicant notes that all the methodology that is discussed by Williams is known methodology; the inventive feature of Williams is not the development of a new method of carrying out a diagnostic test, but rather is the improved method of obtaining the improved antibodies that are used in the test.

Applicant notes that Williams does not at any point in the patent show or suggest the detection of verotoxin together with another substance on the same test strip, as is required in claims 1, 6, and 7 of the present application. Further, Williams does not at any point show or suggest the detection of *E. coli* bacteria by any method whatsoever. The Williams technology is focused on novel methods of producing improved antibodies for use in the treatment of verotoxin related illnesses, and the use of those same antibodies for the detection of verotoxin (and related toxins) in samples. There is no showing or suggestion that the detection of verotoxin could or should be coupled with the detection

of *E. coli* on a single test strip, as is the case for the present invention, nor are the need for or advantages of such a detection system discussed.

Krivan (U.S. patent 5, 512, 282)

The main focus of Krivan is the provision of antibodies to "Shiga-like" toxins or "SLTs" (an alternative nomenclature for verotoxins). At the time of filing of the Krivan application, which was four years prior to Williams, the only method to detect the toxins was a laborious and time-consuming procedure involving determination of cytotoxicity to cells in culture. Not only did the procedure require a lengthy period of time before results could be received, a bona fide cell culture facility was required to carry out the assay (see the Abstract, and column 2, lines 51-62). Krivan states that the point of the invention is that "We have discovered that pregnant cows immunized with purified SLT's produce monospecific, polyclonal antibodies to SLT's that are of a surprisingly and unexpectedly high titer. As a result, we were able to produce very high titer colostrum and milk for use in passive immunization or treatment of SLT toxin." (Column 5, lines 42-47). The text further states that, in contrast to earlier methods, the cows did not experience ill effects as a result of the immunization, so that active toxin could be used for the immunization. As a result, the antibodies that were produced recognized native epitopes and displayed high valency, so that "...as a result of this increased polyvalency, we were able to produce purified IgG that provides outstanding signal to noise ratio when used as reagent in assays for the detection of SLTs." (Column 5, lines 47-56).

Uses of the antibodies described by Krivan include therapeutic, diagnostic, and scientific applications (column 10, lines 28-30). The diagnostic application is discussed in detail beginning in column 11 at lines 38-40, which state that "The IgG and antibodies of the invention are also useful for detecting the presence of one or more SLTs or SLT-producing bacteria in a sample suspected of containing such toxins or bacteria." Applicant notes that the detection of SLT-producing bacteria referred to in this passage must, however, be indirect, i.e. what is actually detected is the toxin (not the bacteria) and the presence of the bacteria can be inferred only from a positive toxin result. (This assumes that typically the only source of the toxin would be a bacteria, and excludes the

possibility of, for example, detecting the direct intake of the toxin itself.) This is because the antibodies produced by the methods of Krivan are not specific for the bacteria, but for the toxin produced by the bacteria. Krivan does not disclose or discuss antibodies that are specific for SLT-producing bacteria, but only for the toxin molecule produced thereby. In fact, Krivan teaches away from detecting the bacteria at all, stating in column 14 at lines23-26: "Because there are over 50 serotypes of verotoxin-producing *E. coli*, any satisfactory overall diagnostic strategy must be directed toward detecting the verotoxin *rather than the organism.*" (Emphasis added.)

Krivan's discussion of detection methods involves several "laundry lists" of potential variations, none of which are meant to convey novelty to the method. Clearly, the point of the invention is not whether the antibodies are immobilized on a particular type of surface (see column 11, lines 53-55 and column 12, lines 1-9), or which type of detection method is used (see column 12, lines 43-52). Rather, the focus of the Krivan invention is on the provision of particularly effective polyvalent antibodies that are specific for Shiga-like toxin molecules.

Applicant submits that a combination of Kouvonen, Williams and Krivan could at best provide a system for detecting the presence of verotoxin in a sample, possibly together with some similar substance. In particular, in view of the teaching of Krivan that the detection of bacteria should not be attempted due to the large number of existing serotypes, such a combination would not include *Escherichia coli*. The system would involve the use of the test strip developed by Kouvonen, and antibodies specific for verotoxin produced either by the improved methods of Williams, or the improved methods of Krivan (or both?). In any case, there would be no reason based on the teachings of these three references, to include detection of the groupings of substances recited in independent claims 1, 6, and 7 of the present invention (verotoxin producing *Escherichia coli* and verotoxin; verotoxin and human hemoglobin; and verotoxin producing *Escherichia coli* and human hemoglobin) since none of the three references alludes to these combinations, or to any advantages that the detection of such combinations in a single test might afford.

In contrast, detection of two or more substances in the same assay or kit is a key feature of the present invention that is not taught or contemplated by the prior art. This process allows the rapid and simple evaluation of both the kind of infection and the extent of pathology associated with the infection. As described above, it is noted on page 2 of the application that "...verotoxin and human hemoglobin associated with internal hemorrhage..." (emphasis added) may be detected simultaneously by the kit of the present invention. Further, Examples 1-16 of the application represent the results of the detection of *E. coli* and/or verotoxin, and/or hemoglobin, which may be present without concurrent infection as in sample 15. Clearly, such an assay method is not rendered obvious by any combination of the cited references.

ARGUMENT VIIE. REJECTION OTHER THAN 35 U.S.C. §§102, 103 AND 112

There are no rejections other than under 35 U.S.C. §§ 102, 103, and 112.

VIII. CLAIMS APPENDIX

The text of the claims involved in this Appeal are:

1. An immunoassay method comprising:

bringing an immobilized phase comprising, at different positions on a water-absorbable base material, at least two different first immunity substances wherein said first immunity substances are specific for assay target substances contained in a test sample that are selected from the group consisting of a combination of verotoxin-producing *Escherichia coli* and verotoxin, a combination of verotoxin and human hemoglobin, and a combination of verotoxin-producing *Escherichia coli* and human hemoglobin, into contact with a test sample and a liquid containing second immunity substances, wherein each of said second immunity substances is labeled with colored latex particles and binds with said assay target substances, thereby to form assay target substance-labeled immunity substance complexes and to bind said complexes with respective first immunity substances at the immobilized phase; and

detecting said labeled immunity substance complex.

2. The immunoassay method of claim 1, wherein the contact is made by flowing the test sample, so that it is absorbed from one end of the water-absorbable base material, thereby to bind said complex with the first immunity substance.

3. The immunoassay method of claim 1, wherein the contact is made by flowing the test sample, so that it is absorbed from one end of the water-absorbable base material, thereby to bind the assay target substance with the first immunity substance, and then flowing the liquid to allow absorption thereof by the base material, thereby to bind said second immunity substance with the assay target substance.

4. The immunoassay method of claim 1, wherein the contact is made by having the test

sample absorbed halfway up to the immobilized phase, allowing the liquid to be absorbed from one end of the water-absorbable base material, thereby to form a complex of said second immunity substance and the assay target substance, and binding said complex with the first immunity substance at the immobilized phase.

5. The immunoassay method of claim 1, wherein contact between the test sample and the second immunity substances is made by positioning a label phase partially up the immobilized phase by adding the liquid containing the second immunity substance partially up the immobilized phase and drying the liquid, the label phase comprising the second immunity substance in such manner that the second immunity substance can be released from the base material upon contact with water, allowing the test sample to be absorbed from one end of the water-absorbable base material, thereby to form a complex of said second immunity substance and the assay target substance, and binding said complex with the first immunity substance at the immobilized phase.

6. An immunoassay device comprising:

an immobilized phase comprising plural first immunity substances each specific for an assay target substance immobilized on a water-absorbable base material; and

a label phase comprising a labeled immunity substance comprising second immunity substances, said second immunity substances are labeled with colored latex particles which bind with one of said assay target substances in such a manner that the second immunity substance can be released from the base material upon contact with water, said immobilized phase comprising at least two different first immunity substances wherein said first immunity substances are specific for assay target substances selected from the group consisting of a combination of verotoxin-producing *Escherichia coli* and verotoxin, a combination of verotoxin and human hemoglobin, and a combination of verotoxin-producing *Escherichia coli* and human hemoglobin contained in a test sample, said first immunity substances being immobilized on different positions on the water-soluble base material.

7. An immunoassay kit comprising:

an immobilized phase comprising, on a water-absorbable base material, plural immobilized first immunity substances each specific for an assay target substance; and

a liquid containing second immunity substances, each of said second immunity substances is labeled with colored latex particles and is specific for one of said assay target substances, said assay target substances being at least two kinds of assay target substances selected from the group consisting of verotoxin-producing *Escherichia coli*, verotoxin and human hemoglobin, wherein the kit is specific for assay target substances selected from the group consisting of a combination of verotoxin-producing *Escherichia coli* and verotoxin, a combination of verotoxin and human hemoglobin, and a combination of verotoxin-producing *Escherichia coli* and human hemoglobin contained in a test sample.

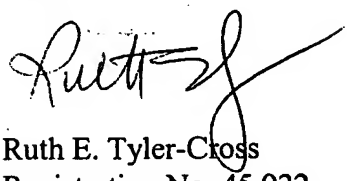
IX. EVIDENCE APPENDIX

No evidence was submitted in this case under 37 C.F.R. 1.130, 1.131, or 1.132, and no evidence was entered separately by the Examiner.

X. RELATED PROCEEDINGS APPENDIX

No decisions have been rendered in any court or by the Board in a related appeal or interference.

Respectfully submitted,



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PART 15 — [Reserved]

[Part 15 removed and reserved, 61 FR 42807, Aug. 19, 1996]

PART 15a — [Reserved]

[Part 15a removed and reserved, 61 FR 42807, Aug. 19, 1996]

PART 41 — PRACTICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Subpart A—General Provisions

GENERAL INFORMATION

Sec.

Subpart B—Ex Parte Appeals

Subpart C—Inter Partes Appeals

Subpart D—Contested Cases

Subpart E—Patent Interferences

Subpart A — General Provisions

§ 41.1 Policy.

(a) *Scope.* Part 41 governs proceedings before the Board of Patent Appeals and Interferences. Sections 1.1 to 1.36 and 1.181 to 1.183 of this title also apply to practice before the Board, as do other sections of part 1 of this title that are incorporated by reference into part 41.

(b) *Construction.* The provisions of Part 41 shall be construed to secure the just, speedy, and inexpensive resolution of every proceeding before the Board.

(c) *Decorum.* Each party must act with courtesy and decorum in all proceedings before the Board, including interactions with other parties.

[Added, 65 FR 52916, Aug. 31, 2000, effective Oct. 2, 2000]

§ 41.2 Definitions.

Unless otherwise clear from the context, the following definitions apply to proceedings under this part:

Affidavit means affidavit, declaration under § 1.68 of this title, or statutory declaration under 28 U.S.C. 1746. A transcript of an ex parte deposition may be used as an affidavit in a contested case.

Board means the Board of Patent Appeals and Interferences and includes:

(1) For a final Board action:

(i) In an appeal or contested case, a panel of the Board.

(ii) In a proceeding under § 41.3, the Chief Administrative Patent Judge or another official acting under an express delegation from the Chief Administrative Patent Judge.

(2) For non-final actions, a Board member or employee acting with the authority of the Board.

Board member means the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, the Deputy Under Secretary of Commerce for Intellectual Property and Deputy Director of the United States Patent and Trademark Office, the Commissioner for Patents, the Commissioner for Trademarks, and the administrative patent judges.

Contested case means a Board proceeding other than an appeal under 35 U.S.C. 134 or a petition under § 41.3. An appeal in an inter partes reexamination is not a contested case.

Final means, with regard to a Board action, final for the purposes of judicial review. A decision is final only if:

(1) *In a panel proceeding.* The decision is rendered by a panel, disposes of all issues with regard to the party seeking judicial review, and does not indicate that further action is required; and

(2) *In other proceedings.* The decision disposes of all issues or the decision states it is final.

Hearing means consideration of the issues of record. *Rehearing* means reconsideration.

Office means United States Patent and Trademark Office.

Panel means at least three Board members acting in a panel proceeding.

Panel proceeding means a proceeding in which final action is reserved by statute to at least three Board members, but includes a non-final portion of such a proceeding whether administered by a panel or not.

Party, in this part, means any entity participating in a Board proceeding, other than officers and employees of the Office, including:

(1) An appellant;

(2) A participant in a contested case;

(3) A petitioner; and

(4) Counsel for any of the above, where context permits.

[Added, 69 FR 49959, Aug. 12, 2004, effective Sept. 13, 2004]

§ 41.3 Petitions.

(a) *Deciding official.* Petitions must be addressed to the Chief Administrative Patent Judge. A panel or an administrative patent judge may certify a question of policy to the Chief Administrative Patent Judge for decision. The Chief Administrative Patent Judge may delegate authority to decide petitions.

(b) *Scope.* This section covers petitions on matters pending before the Board (§§ 41.35, 41.64, 41.103, and 41.205); otherwise, see §§ 1.181 to 1.183 of this title. The following matters are not subject to petition:

(1) Issues committed by statute to a panel, and

(2) In pending contested cases, procedural issues. See § 41.121 (a)(3) and § 41.125 (c).

(c) *Petition fee.* The fee set in § 41.20 (a) must accompany any petition under this section except no fee is required for a petition under this section seeking supervisory review.

(d) *Effect on proceeding.* The filing of a petition does not stay the time for any other action in a Board proceeding.

(e) *Time for action.* (1) Except as otherwise provided in this part or as the Board may authorize in writing, a party may:

(i) File the petition within 14 days from the date of the action from which the party is requesting relief, and

(ii) File any request for reconsideration of a petition decision within 14 days of the decision on petition or such other time as the Board may set.

[Added, 69 FR 49959, Aug. 12, 2004, effective Sept. 13, 2004; para. (e)(1) revised, 69 FR 58260, Sept. 30, 2004, effective Sept. 30, 2004]

§ 41.4 Timeliness.

(a) *Extensions of time.* Extensions of time will be granted only on a showing of good cause except as otherwise provided by rule.

(b) *Late filings.* (1) A late filing that results in either an application becoming abandoned or a reexamination proceeding becoming terminated under §§ 1.550(d) or 1.957(b) or (c) of this title may be revived as set forth in § 1.137 of this title.

(2) A late filing that does not result in either an application becoming abandoned or a reexamination proceeding becoming terminated under §§ 1.550(d) or 1.957(b) or (c) of this title will be excused upon a showing of excusable neglect or a Board determination that consideration on the merits would be in the interest of justice.

(c) *Scope.* This section governs all proceedings before the Board, but does not apply to filings related to Board proceedings before or after the Board has jurisdiction, such as:

(1) Extensions during prosecution (see § 1.136 of this title),

(2) Filing of a brief or request for oral hearing (see §§ 41.37, 41.41, 41.47, 41.67, 41.68, 41.71 and 41.73), or

(3) Seeking judicial review (see §§1.301 to 1.304 of this title).

[Added, 69 FR 49959, Aug. 12, 2004, effective Sept. 13, 2004]

§ 41.5 Counsel.

While the Board has jurisdiction:

(a) *Appearance pro hac vice.* The Board may authorize a person other than a registered practitioner to appear as counsel in a specific proceeding.

(b) *Disqualification.* (1) The Board may disqualify counsel in a specific proceeding after notice and an opportunity to be heard.

(2) A decision to disqualify is not final for the purposes of judicial review until certified by the Chief Administrative Patent Judge.

(c) *Withdrawal.* Counsel may not withdraw from a proceeding before the Board unless the Board authorizes such withdrawal. See § 10.40 of this title regarding conditions for withdrawal.

(d) *Procedure.* The Board may institute a proceeding under this section on its own or a party in a contested case may request relief under this section.

(e) *Referral to the Director of Enrollment and Discipline.* Possible violations of the disciplinary rules in part 10 of this title may be referred to the Office of Enrollment and Discipline for investigation. See § 10.131 of this title.

[Added, 69 FR 49959, Aug. 12, 2004, effective Sept. 13, 2004]

§ 41.6 Public availability of Board records.

(a) *Publication.* (1) *Generally.* Any Board action is available for public inspection without a party's permission if rendered in a file open to the public pursuant to § 1.11 of this title or in an application that has been published in accordance with §§ 1.211 to 1.221 of this title. The Office may independently publish any Board action that is available for public inspection.

(2) *Determination of special circumstances.* Any Board action not publishable under paragraph (a)(1) of this section may be published or made available for public inspection if the Director believes that special circumstances warrant publication and a party does not, within two months after being notified of the intention to make the action public, object in writing on the ground that the action discloses the objecting party's trade secret or other confidential information and states with specificity that such information is not otherwise publicly available. If the action discloses such information, the party shall identify the deletions in the text of the action considered necessary to protect the information. If the affected party considers that the entire action must be withheld from the public to protect such information, the party must explain why. The party will be given time, not less than twenty days, to request reconsideration and seek court review before any contested portion of the action is made public over its objection.

(b) *Record of proceeding.* (1) The record of a Board proceeding is available to the public unless a patent application not otherwise available to the public is involved.

(2) Notwithstanding paragraph (b)(1) of this section, after a final Board action in or judgment in a Board proceeding, the record of the Board proceeding will be made available to the public if any involved file is or becomes open to the public under § 1.11 of this title or an involved application is or becomes published under §§ 1.211 to 1.221 of this title.

[Added, 69 FR 49959, Aug. 12, 2004, effective Sept. 13, 2004]

§ 41.7 Management of the record.

(a) The Board may expunge any paper directed to a Board proceeding, or filed while an application or patent is under the jurisdiction of the Board, that is not authorized under this part or in a Board order, or that is filed contrary to a Board order.

(b) A party may not file a paper previously filed in the same Board proceeding, not even as an exhibit or appendix, without Board authorization or as required by rule.

[Added, 69 FR 49959, Aug. 12, 2004, effective Sept. 13, 2004]

§ 41.8 Mandatory notices.

(a) In an appeal brief (§§ 41.37, 41.67, or 41.68) or at the initiation of a contested case (§ 41.101), and within 20 days of any change during the proceeding, a party must identify:

(1) Its real party-in-interest, and

(2) Each judicial or administrative proceeding that could affect, or be affected by, the Board proceeding.

(b) For contested cases, a party seeking judicial review of a Board proceeding must file a notice with the Board of the judicial review within 20 days of the filing of the complaint or the notice of appeal. The notice to the Board must include a copy of the complaint or notice of appeal. See also §§ 1.301 to 1.304 of this title.

[Added, 69 FR 49959, Aug. 12, 2004, effective Sept. 13, 2004]

§ 41.9 Action by owner.

(a) *Entire interest.* An owner of the entire interest in an application or patent involved in a Board proceeding may act in the proceeding to the exclusion of the inventor (see 3.73 (b) of this title).

(b) *Part interest.* An owner of a part interest in an application or patent involved in a Board proceeding may petition to act in the proceeding to the exclusion of an inventor or a co-owner. The petition must show the inability or refusal of an inventor or co-owner to prosecute the proceeding or other cause why it is in the interest of justice to permit the owner of a part interest to act in the proceeding. An order granting the petition may set conditions on the actions of the parties during the proceeding

[Added, 69 FR 49959, Aug. 12, 2004, effective Sept. 13, 2004]

§ 41.10 Correspondence addresses.

Except as the Board may otherwise direct,

(a) *Appeals.* Correspondence in an application or a patent involved in an appeal (subparts B and C of this part) during the period beginning when an appeal docketing notice is issued and ending when a decision has been rendered by the Board, as well as any request for rehearing of a decision by the Board, shall be mailed to: Board of Patent Appeals and Interferences, United States Patent and Trademark Office, PO Box 1450, Alexandria, Virginia 22313-1450. Notices of appeal, appeal briefs, reply briefs, requests for oral hearing, as well as all other correspondence in an application or a patent involved in an appeal to the Board for which an address is not otherwise specified, should be addressed as set out in § 1.1 (a)(1)(i) of this title.

(b) *Contested cases.* Mailed correspondence in contested cases (subpart D of this part) shall be sent to Mail Stop INTERFERENCE, Board of Patent Appeals and Interferences, United States Patent and Trademark Office, PO Box 1450, Alexandria, Virginia 22313-1450.

[Added, 69 FR 49959, Aug. 12, 2004, effective Sept. 13, 2004]

§ 41.11 Ex parte communications in inter partes proceedings.

An ex parte communication about an inter partes reexamination (subpart C of this part) or about a contested case (subparts D and E of this part) with a Board member, or with a Board employee assigned to the proceeding, is not permitted.

[Added, 69 FR 49959, Aug. 12, 2004, effective Sept. 13, 2004]

§ 41.12 Citation of authority.

(a) Citations to authority must include:

(1) *For any United States Supreme Court decision,* a United States Reports citation.

(2) *For any decision other than a United States Supreme Court decision,* parallel citation to both the West Reporter System and to the United States Patents Quarterly whenever the case is published in both. Other parallel citations are discouraged.

(3) *Pinpoint citations* whenever a specific holding or portion of an authority is invoked.

(b) Non-binding authority should be used sparingly. If the authority is not an authority of the Office and is not reproduced in one of the reporters listed in paragraph (a) of this section, a copy of the authority should be filed with the first paper in which it is cited.

[Added, 69 FR 49959, Aug. 12, 2004, effective Sept. 13, 2004]

§ 41.20 Fees.

(a) *Petition fee.* The fee for filing a petition under this part is: $400.00

(b) *Appeal fees.* (1) For filing a notice of appeal from the examiner to the Board:

By a small entity (§ 1.27(a) of this title) $250.00

By other than a small entity $500.00

(2) In addition to the fee for filing a notice of appeal, for filing a brief in support of an appeal:

By a small entity (§ 1.27(a) of this title) $250.00

By other than a small entity $500.00

(3) For filing a request for an oral hearing before the Board in an appeal under 35 U.S.C. 134:

By a small entity (§ 1.27(a) of this title) $500.00

By other than a small entity . . . $1,000.00

[Added, 69 FR 49959, Aug. 12, 2004, effective Sept. 13, 2004; paras. (b)(1) through (b)(3) revised, 69 FR 52604, Aug. 27, 2004, effective Oct. 1, 2004; para. (b)(3) corrected, 69 FR 55505, Sept. 15, 2004, effective Oct. 1, 2004; para. (a) revised, 69 FR 56481, Sept. 21, 2004, effective Nov. 22, 2004; para. (b) revised, 70 FR 3880, Jan. 27, 2005, effective Dec. 8, 2004]

Subpart B — Ex Parte Appeals

§ 41.30 Definitions.

In addition to the definitions in § 41.2, the following definitions apply to proceedings under this subpart unless otherwise clear from the context:

Applicant means either the applicant in a national application for a patent or the applicant in an application for reissue of a patent.

Owner means the owner of the patent undergoing ex parte reexamination under § 1.510 of this title.

Proceeding means either a national application for a patent, an application for reissue of a patent, or an *ex parte* reexamination proceeding. Appeal to the Board in an *inter partes* reexamination proceeding is controlled by subpart C of this part.

[Added, 69 FR 49959, Aug. 12, 2004, effective Sept. 13, 2004]

§ 41.31 Appeal to Board.

(a) *Who may appeal and how to file an appeal.* (1) Every applicant, any of whose claims has been twice rejected, may appeal from the decision of the examiner to the Board by filing a notice of appeal accompanied by the fee set forth in § 41.20(b)(1) within the time period provided under § 1.134 of this title for reply.

(2) Every owner of a patent under *ex parte* reexamination filed under § 1.510 of this title before November 29, 1999, any of whose claims has been twice rejected, may appeal from the decision of the examiner to the Board by filing a notice of appeal accompanied by the fee set forth in § 41.20(b)(1) within the time period provided under § 1.134 of this title for reply.

(3) Every owner of a patent under *ex parte* reexamination filed under § 1.510 of this title on or after November 29, 1999, any of whose claims has been finally (§ 1.113 of this title) rejected, may appeal from the decision of the examiner to the Board by filing a notice of appeal accompanied by the fee set forth in § 41.20(b)(1) within the time period provided under § 1.134 of this title for reply.

(b) The signature requirement of § 1.33 of this title does not apply to a notice of appeal filed under this section.

(c) An appeal, when taken, must be taken from the rejection of all claims under rejection which the applicant or owner proposes to contest. Questions relating to matters not affecting the merits of the invention may be required to be settled before an appeal can be considered.

(d) The time periods set forth in paragraphs (a)(1) through (a)(3) of this section are extendable under the provisions of § 1.136 of this title for patent applications and § 1.550(c) of this title for ex parte reexamination proceedings.

[Added, 69 FR 49959, Aug. 12, 2004, effective Sept. 13, 2004]

§ 41.33 Amendments and affidavits or other evidence after appeal.

(a) Amendments filed after the date of filing an appeal pursuant to § 41.31(a)(1) through (a)(3) and prior to the date a brief is filed pursuant to § 41.37 may be admitted as provided in § 1.116 of this title.

(b) Amendments filed on or after the date of filing a brief pursuant to § 41.37 may be admitted:

(1) To cancel claims, where such cancellation does not affect the scope of any other pending claim in the proceeding, or

(2) To rewrite dependent claims into independent form.

(c) All other amendments filed after the date of filing an appeal pursuant to § 41.31(a)(1) through (a)(3) will not be admitted except as permitted by §§ 41.39(b)(1), 41.50(a)(2)(i), 41.50(b)(1) and 41.50(c).

(d)(1) An affidavit or other evidence filed after the date of filing an appeal pursuant to § 41.31(a)(1) through (a)(3) and prior to the date of filing a brief pursuant to § 41.37 may be admitted if the examiner determines that the affidavit or other evidence overcomes all rejections under appeal and that a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented has been made.

(2) All other affidavits or other evidence filed after the date of filing an appeal pursuant to § 41.31(a)(1) through (a)(3) will not be admitted except as permitted by §§ 41.39(b)(1), 41.50(a)(2)(i) and 41.50(b)(1).

[Added, 69 FR 49959, Aug. 12, 2004, effective Sept. 13, 2004]

§ 41.35 Jurisdiction over appeal.

(a) Jurisdiction over the proceeding passes to the Board upon transmittal of the file, including all briefs and examiner's answers, to the Board.

(b) If, after receipt and review of the proceeding, the Board determines that the file is not complete or is not in compliance with the requirements of this subpart, the Board may relinquish jurisdiction to the examiner or take other appropriate action to permit completion of the file.

(c) Prior to the entry of a decision on the appeal by the Board, the Director may sua sponte order the proceeding remanded to the examiner.

[Added, 69 FR 49959, Aug. 12, 2004, effective Sept. 13, 2004]

§ 41.37 Appeal brief.

(a)(1)Appellant must file a brief under this section within two months from the date of filing the notice of appeal under § 41.31.

(2) The brief must be accompanied by the fee set forth in § 41.20(b)(2)

(b) On failure to file the brief, accompanied by the requisite fee, within the period specified in paragraph (a) of this section, the appeal will stand dismissed.

(c)(1)The brief shall contain the following items under appropriate headings and in the order indicated in paragraphs (c)(1)(i) through (c)(1)(x) of this section, except that a brief filed by an appellant who is not represented by a registered practitioner need only substantially comply with paragraphs (c)(1)(i) through (c)(1)(iv) and (c)(1)(vii) through (c)(1)(x) of this section:

(i) *Real party in interest.* A statement identifying by name the real party in interest.

(ii) *Related appeals and interferences.* A statement identifying by application, patent, appeal or interference number all other prior and pending appeals, interferences or judicial proceedings known to appellant, the appellant's legal representative, or assignee which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal. Copies of any decisions rendered by a court or the Board in any proceeding identified under this paragraph must be included in an appendix as required by paragraph (c)(1)(x) of this section.

(iii) *Status of claims.* A statement of the status of all the claims in the proceeding (*e.g.*, rejected, allowed or confirmed, withdrawn, objected to, canceled) and an identification of those claims that are being appealed.

(iv) *Status of amendments.* A statement of the status of any amendment filed subsequent to final rejection.

(v) *Summary of claimed subject matter.* A concise explanation of the subject matter defined in each of the independent claims involved in the appeal, which shall refer to the specification by page and line number, and to the drawing, if any, by reference characters. For each independent claim involved in the appeal and for each dependent claim argued separately under the provisions of paragraph (c)(1)(vii) of this section, every means plus function and step plus function as permitted by 35 U.S.C. 112, sixth paragraph, must be identified and the structure, material, or acts described in the specification as corresponding to each claimed function must be set forth with reference to the specification by page and line number, and to the drawing, if any, by reference characters.

(vi) *Grounds of rejection to be reviewed on appeal.* A concise statement of each ground of rejection presented for review.

(vii) *Argument.* The contentions of appellant with respect to each ground of rejection presented for review in paragraph (c)(1)(vi) of this section, and the basis therefor, with citations of the statutes, regulations, authorities, and parts of the record relied on. Any arguments or authorities not included in the brief or a reply brief filed pursuant to § 41.41 will be refused consideration by the Board, unless good cause is shown. Each ground of rejection must be treated under a separate heading. For each ground of rejection applying to two or more claims, the claims may be argued separately or as a group. When multiple claims subject to the same ground of rejection are argued as a group by appellant, the Board may select a single claim from the group of claims that are argued together to decide the appeal with respect to the group of claims as to the ground of rejection on the basis of the selected claim alone. Notwithstanding any other provision of this paragraph, the failure of appellant to separately argue claims which appellant has grouped together shall constitute a waiver of any argument that the Board must consider the patentability of any grouped claim separately. Any claim argued separately should be placed under a subheading identifying the claim by number. Claims argued as a group should be placed under a subheading identifying the claims by number. A statement which merely points out what a claim recites will not be considered an argument for separate patentability of the claim.

(viii) *Claims appendix.* An appendix containing a copy of the claims involved in the appeal.

(ix) *Evidence appendix.* An appendix containing copies of any evidence submitted pursuant to §§ 1.130, 1.131, or 1.132 of this title or of any other evidence entered by the examiner and relied upon by appellant in the appeal, along with a statement setting forth where in the record that evidence was entered in the record by the examiner. Reference to unentered evidence is not permitted in the brief. See § 41.33 for treatment of evidence submitted after appeal. This appendix may also include copies of the evidence relied upon by the examiner as to grounds of rejection to be reviewed on appeal.

(x) *Related proceedings appendix.* An appendix containing copies of decisions rendered by a court or the Board in any proceeding identified pursuant to paragraph (c)(1)(ii) of this section.

(2) A brief shall not include any new or non-admitted amendment, or any new or non-admitted affidavit or other evidence. See § 1.116 of this title for amendments, affidavits or other evidence filed after final action but before or on the same date of filing an appeal and § 41.33 for amendments, affidavits or other evidence filed after the date of filing the appeal.

(d) If a brief is filed which does not comply with all the requirements of paragraph (c) of this section, appellant will be notified of the reasons for non-compliance and given a time period within which to file an amended brief. If appellant does not file an amended brief within the set time period, or files an amended brief which does not overcome all the reasons for non-compliance stated in the notification, the appeal will stand dismissed.

(e) The time periods set forth in this section are extendable under the provisions of § 1.136 of this title for patent applications and § 1.550(c) of this title for ex parte reexamination proceedings.

[Added, 69 FR 49959, Aug. 12, 2004, effective Sept. 13, 2004]

§ 41.39 Examiner's answer.

(a)(1)The primary examiner may, within such time as may be directed by the Director, furnish a written answer to the appeal brief including such explanation of the invention claimed and of the references relied upon and grounds of rejection as may be necessary, supplying a copy to appellant. If the primary examiner determines that the appeal does not comply with the provisions of §§ 41.31 and 41.37 or does not relate to an appealable action, the primary examiner shall make such determination of record.

(2) An examiner's answer may include a new ground of rejection.

(b) If an examiner's answer contains a rejection designated as a new ground of rejection, appellant must within two months from the date of the examiner's answer exercise one of the following two options to avoid sua sponte dismissal of the appeal as to the claims subject to the new ground of rejection:

(1) *Reopen prosecution.* Request that prosecution be reopened before the primary examiner by filing a reply under § 1.111 of this title with or without amendment or submission of affidavits (§§ 1.130, 1.131 or 1.132 of this title) or other evidence. Any amendment or submission of affidavits or other evidence must be relevant to the new ground of rejection. A request that complies with this paragraph will be entered and the application or the patent under ex parte reexamination will be reconsidered by the examiner under the provisions of § 1.112 of this title. Any request that prosecution be reopened under this paragraph will be treated as a request to withdraw the appeal.

(2) *Maintain appeal.* Request that the appeal be maintained by filing a reply brief as set forth in § 41.41. Such a reply brief must address each new ground of rejection as set forth in § 41.37(c)(1)(vii) and should follow the other requirements of a brief as set forth in § 41.37(c). A reply brief may not be accompanied by any amendment, affidavit (§§ 1.130, 1.131 or 1.132 of this title) or other evidence. If a reply brief filed pursuant to this section is accompanied by any amendment, affidavit or other evidence, it shall be treated as a request that prosecution be reopened before the primary examiner under paragraph (b)(1) of this section.

(c) Extensions of time under § 1.136 (a) of this title for patent applications are not applicable to the time period set forth in this section. See § 1.136 (b) of this title for extensions of time to reply for patent applications and § 1.550 (c) of this title for extensions of time to reply for ex parte reexamination proceedings.

[Added, 69 FR 49959, Aug. 12, 2004, effective Sept. 13, 2004]

§ 41.41 Reply brief.

(a)(1)Appellant may file a reply brief to an examiner's answer within two months from the date of the examiner's answer.

(2) A reply brief shall not include any new or non-admitted amendment, or any new or non-admitted affidavit or other evidence. See § 1.116 of this title for amendments, affidavits or other evidence filed after final action but before or on the same date of filing an appeal and § 41.33 for amendments, affidavits or other evidence filed after the date of filing the appeal.

(b) A reply brief that is not in compliance with paragraph (a) of this section will not be considered. Appellant will be notified if a reply brief is not in compliance with paragraph (a) of this section.

(c) Extensions of time under § 1.136 (a) of this title for patent applications are not applicable to the time period set forth in this section. See § 1.136 (b) of this title for extensions of time to reply for patent applications and § 1.550 (c) of this title for extensions of time to reply for ex parte reexamination proceedings.

[Added, 69 FR 49959, Aug. 12, 2004, effective Sept. 13, 2004]

§ 41.43 Examiner's response to reply brief.

(a)(1)After receipt of a reply brief in compliance with § 41.41, the primary examiner must acknowledge receipt and entry of the reply brief. In addition, the primary examiner may withdraw the final rejection and reopen prosecution or may furnish a supplemental examiner's answer responding to any new issue raised in the reply brief.

(2) A supplemental examiner's answer responding to a reply brief may not include a new ground of rejection.

(b) If a supplemental examiner's answer is furnished by the examiner, appellant may file another reply brief under § 41.41 to any supplemental examiner's answer within two months from the date of the supplemental examiner's answer.

(c) Extensions of time under § 1.136(a) of this title for patent applications are not applicable to the time period set forth in this section. See § 1.136(b) of this title for extensions of time to reply for patent applications and § 1.550(c) of this title for extensions of time to reply for ex parte reexamination proceedings.

[Added, 69 FR 49959, Aug. 12, 2004, effective Sept. 13, 2004]

§ 41.47 Oral hearing.

(a) An oral hearing should be requested only in those circumstances in which appellant considers such a hearing necessary or desirable for a proper presentation of the appeal. An appeal decided on the briefs without an oral hearing will receive the same consideration by the Board as appeals decided after an oral hearing.

(b) If appellant desires an oral hearing, appellant must file, as a separate paper captioned "REQUEST FOR ORAL HEARING," a written request for such hearing accompanied by the fee set forth in § 41.20(b)(3) within two months from the date of the examiner's answer or supplemental examiner's answer.

(c) If no request and fee for oral hearing have been timely filed by appellant as required by paragraph (b) of this section, the appeal will be assigned for consideration and decision on the briefs without an oral hearing.

(d) If appellant has complied with all the requirements of paragraph (b) of this section, a date for the oral hearing will be set, and due notice thereof given to appellant. If an oral hearing is held, an oral argument may be presented by, or on behalf of, the primary examiner if considered desirable by either the primary examiner or the Board. A hearing will be held as stated in the notice, and oral argument will ordinarily be limited to twenty minutes for appellant and fifteen minutes for the primary examiner unless otherwise ordered.

(e)(1)Appellant will argue first and may reserve time for rebuttal. At the oral hearing, appellant may only rely on evidence that has been previously entered and considered by the primary examiner and present argument that has been relied upon in the brief or reply brief except as permitted by paragraph (e)(2) of this section. The primary examiner may only rely on argument and evidence relied upon in an answer or a supplemental answer except as permitted by paragraph (e)(2) of this section.

(2) Upon a showing of good cause, appellant and/or the primary examiner may rely on a new argu-